

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

**BAYER INTELLECTUAL PROPERTY
GMBH and BAYER PHARMA AG**

Plaintiffs,

VS.

**WARNER CHILCOTT COMPANY,
LLC, WARNER CHILCOTT (US), LLC,
and WARNER CHILCOTT PLC**

Defendants.

C. A. No. 12-1032-GMS

**PLAINTIFFS' ANSWERING BRIEF IN OPPOSITION TO
WARNER CHILCOTT'S MOTION TO DISMISS**

April 4, 2013

BAYARD, P.A.

OF COUNSEL:

Richard D. Kirk (rk0922)

Matthew R. Ford
Andrew C. MacNally
BARTLIT BECK HERMAN
PALENCHAR & SCOTT LLP
54 W. Hubbard Street, Suite 300
Chicago, IL 60654
(312) 494-4400

Stephen B. Brauerman (sb4952)
Vanessa R. Tiradentes (vt5398)
222 Delaware Avenue, Suite 900
P.O. Box 25130
Wilmington, DE 19899
(302) 655-5000
rkirk@bayardlaw.com
sbrauerman@bayardlaw.com
vtiradentes@bayardlaw.com

*Attorneys for Bayer Intellectual Property GmbH
and Bayer Pharma AG*

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A patent confers a right to exclude others from making, using, or selling the patented subject matter. If two patents give the same right to exclude, both patents are impaired. One party has an invalid patent because someone else conceived of the patented invention first. And the second party lacks full enjoyment of its right to exclude because another patent confers the same right on someone else.

Congress created a statutory right for a patent owner to resolve any such impairment through the courts. Section 291 provides:

The owner of an interfering patent may have relief against the owner of another by civil action, and the court may adjudge the question of the validity of any of the interfering patents, in whole or in part.

35 U.S.C. § 291. In resolving an interference claim, a court first determines whether the patents in fact confer the same right to exclude by claiming the same subject matter. The court then decides which party is entitled to the exclusionary right by determining which party was the first to invent. The court provides “relief” under the statute through “a declaration of priority and the subsequent elimination of an invalid patent that claims the same subject matter as claimed in one’s patent. . . .” *Kimberly-Clark Corp. v. Procter & Gamble Distrib. Co., Inc.*, 973 F.2d 911, 914 (Fed. Cir. 1992).

Warner Chilcott’s motion to dismiss fails because it is based on a misunderstanding of a section 291 interference action. A patent is a property right that allows the patentee to exclude others from practicing the patent. Any impairment to that property right is an injury. The existence of an interfering patent impairs the full enjoyment of the right to exclude because it confers the same right to exclude on another. An interference action removes the impairment by invalidating the later patent. Bayer’s Complaint alleges that it owns the ’940 patent, claims that Warner Chilcott’s patent interferes, identifies the interfering subject matter, and seeks an order invalidating Warner Chilcott’s patent. Those allegations establish Article III standing.

In addition, the Court should deny Warner Chilcott's request for a stay. Warner Chilcott asks the Court to stay Bayer's interference action to await: (1) an unscheduled bench trial; (2) the time for the district court to issue a written decision; (3) post-trial motions; (4) the notice of appeal; (5) the briefing and argument schedule in the Federal Circuit; (6) the time for the Federal Circuit to issue a written decision; and (7) any post-appeal procedures. This process may not end until the eve of the '940 patent's expiration (or later). In tandem with this delay, Bayer would have to watch an unmotivated generic drug company serve as an inadequate proxy for Bayer's interests. And even after this delay, it is unlikely that the New Jersey litigation will have resolved any issues raised in Bayer's interference count given the differences between an interference-in-fact inquiry and an invalidity defense. A stay would subvert Bayer's rights in its patent with no corresponding gains.

The Court should deny Warner Chilcott's motions.

FACTUAL BACKGROUND

I. THE PATENTS IN SUIT

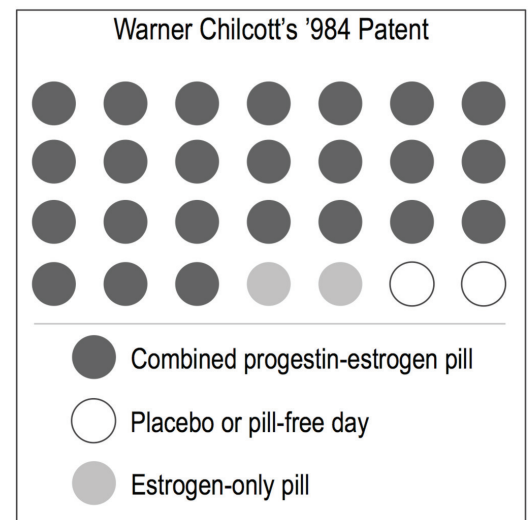
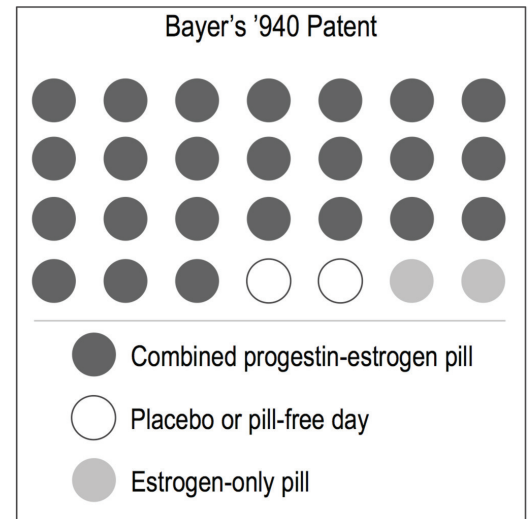
Bayer has asserted U.S. Patent No. 5,980,940 ("940 patent") against Warner Chilcott. (D.I. 5, 12/18/2012 Am. Compl.) Bayer alleges both that Warner Chilcott's Lo Loestrin FE product infringes the '940 patent and that the patent purportedly covering Lo Loestrin FE interferes with the '940 patent. (*Id.* at ¶¶ 23-30.)

The patents in this lawsuit concern contraceptive regimens. Bayer's '940 patent covers an oral contraceptive regimen and a method of contraception. Most oral contraceptives contain two hormones as active ingredients: a progestin and an estrogen. The traditional oral-contraceptive regimen consists of 21 days of a combined progestin-estrogen pill followed by 7 pill-free days (or placebos). The 7-day pill-free period developed for both social and perceived medical reasons. The 7-day break from the hormone pills results in a "withdrawal bleed," a

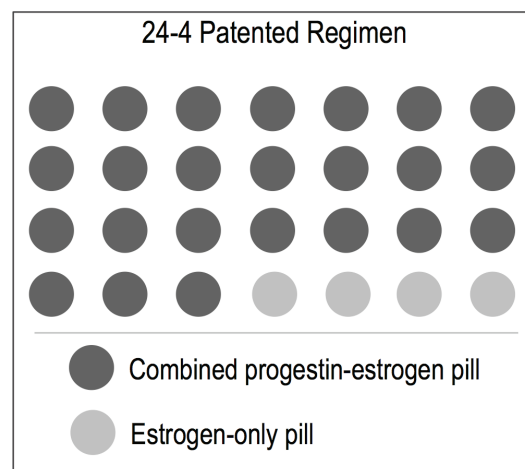
process meant to mimic a woman's monthly menstruation and assure a woman that she was not pregnant. As the regimen gained universal acceptance within the medical community, doctors also began to assign medical significance to the pill-free hormonal break. (Ex. 1, '940 Patent 1:32-45.)

The regimen claimed by the '940 patent is different from the traditional regimen. It claims 24 days of a combined progestin-estrogen pill followed by 2 days of a placebo and 2 days of a low-dose estrogen-only pill. (*Id.* at 7:10-39.) Bayer filed its application to patent this 24-2-2 regimen in 1996, and the patent issued in 1999. (*Id.* at 1.)

Bayer alleges that the '940 patent interferes with Warner Chilcott's patent—U.S. Patent No. 7,704,984 ("'984 patent"). (D.I. 5, Am. Compl. ¶¶ 25-30.) The '984 patent also claims a contraceptive regimen. It claims 24 days of a combined progestin-estrogen pill followed by two days of a low-dose estrogen-only pill and 2 days of a placebo. (Ex. 2, '984 Patent 6:23-36.) Warner Chilcott's regimen differs from that laid out in the '940 patent only in the placement of the placebo pills.



Warner Chilcott failed to cite Bayer's patent during the prosecution of the '984 patent. (D.I. 5, 12/18/2012 Amend. Compl. ¶ 22.) And that omission before the PTO proved consequential. Bayer had pioneered the development of the 24-day regimen, which eventually resulted in the marketing of its blockbuster oral contraceptive, YAZ. As part of that work, Bayer obtained patents on other forms of the 24-day regimen it had discovered. One such patent was U.S. Patent No. 5,756,490 ("'490 patent" or the "24-4 patent"). The 24-4 patent claims a regimen with 24 days of progestin-estrogen pills followed by 4 low-dose estrogen-only pills. (Ex. 3, '490 Patent 7:64-8:15.)



As discussed in Bayer's Complaint, the Patent and Trademark Office rejected Warner Chilcott's application in light of the 24-4 patent. (Ex. 4, 11/2/2009 Final Rejection at 4.) The Examiner concluded that it would have been obvious to breakup the 4-day period of estrogen-only pills by introducing a placebo:

[B]reaks in steroid administration are common in the oral contraceptive art Thus, the skilled artisan would recognize that placebo compositions can be incorporated in oral contraceptive methods without reducing the methods' effectiveness" and "[t]he art worker would understand that a placebo can be administered given the prevalence of placebo phases in the oral contraceptive art."

(*Id.*) On this basis, the Examiner rejected Warner Chilcott's application.

Warner Chilcott responded to this rejection by claiming that the introduction of placebos into the 4-day administration of low-dose estrogen pills was novel. (Ex. 5, 1/14/2010 Warner Chilcott Arguments at 7.) According to Warner Chilcott, a person of skill in the art would not have introduced a pill-free or placebo period to the 24-4 regimen. (*Id.*) In fact, Warner Chilcott said that introducing such a period would have been expected to "negatively impact[]

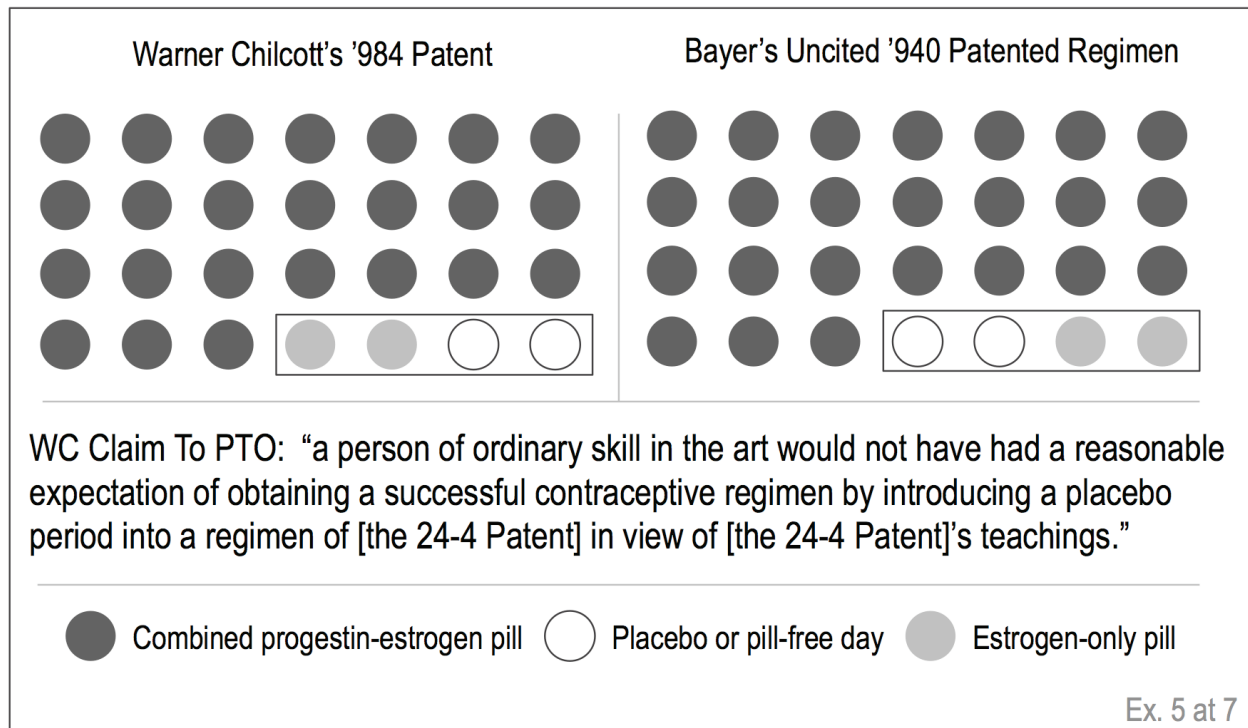
contraceptive efficacy.” (*Id.*) Warner Chilcott did not mention the placement of the two placebos within the 4-day period in defending the novelty of the ’984 patent. (*Id.*)

The Examiner allowed Warner Chilcott’s claims, crediting Warner Chilcott’s efforts to differentiate its application over Bayer’s 24-4 patent based on the introduction of placebos.

Applicant asserts that one of ordinary skill in the art would not have selected a low level ethinyl estradiol in the dosage range disclosed by [Bayer’s 24-4 patent], and introduced a pill-free or placebo period. After careful consideration, Examiner finds Applicant’s arguments persuasive.

(Ex. 6, 2/12/2010 Notice of Allowance at 2-3 (emphasis in original).)

The prosecution history makes clear that what Warner Chilcott claimed was novel about the ’984 patent was invented a decade earlier by Bayer in the ’940 patent. But the similarities go beyond the imposition of a placebo into the 4-day break following the administration of 24 combined estrogen-progestin pills. Bayer’s patent not only embodies what Warner Chilcott said was novel about the ’984 patent—it does so with the same hormones at overlapping and equivalent doses. (*Compare* Ex. 1, ’940 Patent 7-8 *with* Ex. 2, ’984 Patent 6:23-36.)



Ex. 5 at 7

II. PROCEDURAL HISTORY AND BAYER'S COMPLAINT

Warner Chilcott markets an oral contraceptive called Lo Loestrin FE, which embodies the '984 patent. (D.I. 5, Am. Compl. ¶ 15.) Generic-drug manufacturers Watson and Lupin are seeking to market a generic version of Lo Loestrin FE. (D.I. 8, Br. In Support Of Mot. To Dismiss at 6-7 ("WC Br.")). Warner Chilcott is involved in patent litigation with those companies in New Jersey, asserting the '984 patent and another patent against the generics. (*Id.*)

Bayer filed suit against Warner Chilcott in August 13, 2012. (D.I. 1, 8/13/2012 Compl.) The parties met to discuss the possibility of settlement, and when settlement prospects fell through, Bayer served its complaint on December 6, 2012. (D.I. 4, 12/11/2012 Executed Summons.) Bayer amended its complaint on December 18, 2012, adding an interference count. (D.I. 5, 12/18/2012 Am. Compl.)

ARGUMENT

I. BAYER HAS ARTICLE III STANDING TO MAINTAIN AN INTERFERENCE ACTION

An interference action under section 291 involves a two-step inquiry. The first step is to determine whether an interference-in-fact exists between the claims of the two patents. *Medichem, S.A. v. Rolabo, S.L.*, 353 F.3d 928, 934 (Fed. Cir. 2003). An interference-in-fact is jurisdictional, and if an interference is lacking, the Court dismisses the claim. *Id.* ("A district court has no jurisdiction under § 291 unless interference is established.") (citation omitted).

Determining whether an interference-in-fact exists requires application of a "two-way test." *Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1302 (Fed. Cir. 2011). The two-way test proceeds as follows:

The claimed invention of Party A is presumed to be prior art vis-à-vis Party B and vice versa. The claimed invention of Party A must anticipate or render obvious the claimed invention of Party B and the claimed invention of Party B must anticipate or render obvious the claimed invention of Party A.

Medichem, S.A., 353 F.3d at 934. As part of this analysis, the Court only examines the claims of the respective patents to determine whether an interference-in-fact exists. *Slip Track Sys., Inc. v. Metal-Lite, Inc.*, 304 F.3d 1256, 1265 (Fed. Cir. 2002). Once the Court determines that an interference-in-fact exists, the Court determines which party was the first to invent. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1169 (Fed. Cir. 2006).

A. Bayer Has Sufficiently Pled An Interference Action Under Section 291

The allegations in Bayer's Complaint suffice to plead an interference action, and Warner Chilcott makes no suggestion to the contrary. Section 291 provides:

The owner of an interfering patent may have relief against the owner of another by civil action, and the court may adjudge the question of the validity of any of the interfering patents, in whole or in part.

35 U.S.C. § 291. Bayer's Complaint alleges that: (1) Bayer owns the '940 patent (D.I. 5, Am. Compl. ¶ 12.); (2) Warner Chilcott owns the '984 patent (*Id.* ¶¶ 2, 16-22); and (3) the '940 patent and the '984 patent claim the same subject matter, and therefore, interfere (*Id.* ¶¶ 26-30).

These elements are all that are required to plead interference under section 291. *See Datex-Ohmeda, Inc. v. Hill-Rom Services, Inc.*, 185 F. Supp. 2d 407, 410-11 (D. Del. 2002) ("In its Complaint, Datex alleges that the '935 patent and the '606 patent interfere. Datex alleges that the independent claims of the '935 patent and claim 1 of the '606 patent claim the same subject matter, an infant warming device for medical use, and therefore, interfere. The Court is persuaded that Datex has sufficiently pled interference and, therefore, subject matter jurisdiction under 35 U.S.C. § 291.").

B. The Statutory Requirements For Interference Suffice Under Article III

If a patent owner pleads the statutory elements of an interference action, it has pled Article III standing. The existence of an interfering patent impairs the patent owner's undivided

right to exclude under the patent. Invalidating the interfering patent redresses that injury by eliminating the impairment.

The standing analysis applied to a quiet title action is illustrative. *See Utah ex. rel. Div. of Forestry, Fire & State Lands v. United States*, 528 F.3d 712 (10th Cir. 2008). In *Utah*, the state sued under a quiet-title statute to establish the boundary line of a lakebed. The statute required Utah to allege “title, entitlement to possession, and that the estate or interest claimed by others is adverse or hostile to the alleged claims of title or interest.” *Id.* at 721. The defendants challenged Utah’s standing under Article III. The Tenth Circuit rejected that challenge, holding that “the adverse interests asserted by Utah and [defendants] to the property between the meander lines are sufficient to establish Utah’s standing” under Article III. *Id.* at 722.

Similarly, an interference action seeks to restore a patent owner’s full enjoyment of its property as against the adverse claims of the interfering patent holder. **First**, the existence of an interfering patent impairs Bayer’s rights in the ’940 patent. Impairment to a property right is an injury-in-fact. *Toll Bros., Inc. v. Twp. of Readington*, 555 F.3d 131, 142 (3d Cir. 2009) (“This harm to Toll Brothers’ *own* property is a classic form of economic injury.”) (emphasis in original); *see also* Charles Alan Wright, et al., 13A Fed. Prac. & Proc. Juris. § 3531.4 (3d ed.) (“Standing is found readily, particularly when injury to some traditional form of property is asserted.”). And “[i]t is beyond reasonable debate that patents are property.” *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 599 (Fed. Cir. 1985); *see also* *Consol. Fruit-Jar Co. v. Wright*, 94 U.S. 92, 96 (1876) (“A patent for an invention is as much property as a patent for land. The right rests on the same foundation, and is surrounded and protected by the same sanctions.”).

The essential right conferred by a patent is an undivided right to exclude others from practicing the claimed subject matter. *See* 35 U.S.C. § 154 (“Every patent shall contain a short

title of the invention and a *grant to the patentee*, his heirs or assigns, of *the right to exclude others* from making, using, offering for sale, or selling the invention”) (emphasis added); *see also Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). “The fact that the Patent and Trademark Office issued patents . . . on the same invention is a serious impediment to the enjoyment of this essential right to exclude.” *Kimberly-Clark Corp.*, 973 F.2d at 914; 4 Annotated Patent Digest § 26:92 (“The ability to conduct such a proceeding is necessary to protect the enjoyment of patent rights in situations where the Patent Office has erroneously permitted two patents to issue on the same subject matter.”).

A patent owner does not need to make any additional allegation apart from the existence of an interfering patent to plead injury under section 291. The injury to Bayer’s right to exclude under the ’940 patent is the necessary consequence of Warner Chilcott’s interfering patent. The right to exclude conferred by Bayer’s patent is no longer exclusive as Warner Chilcott can claim the same right. And “[n]either patent owner knows if its patent is valid in light of the other’s patent, the presumption of validity provided by 35 U.S.C. § 282 having been eroded by the grant of an ‘interfering’ patent.” *Kimberly-Clark*, 973 F.2d at 914.

Second, an interference proceeding is an independent cause of action that provides distinct relief based on the impairment of a patentee’s undivided right to exclude. Courts have long recognized the need for interference actions to preserve the exclusionary right conferred by a patent. *See EMERSON STRINGHAM, PATENT INTERFERENCE EQUITY SUITS* 20 (1930) (“To the complete enjoyment of his monopoly the extinguishment of the unlawful interfering patent becomes necessary, and as no power has been bestowed upon the Patent Office to recall it, the statutes have provided a specific method for securing its repeal.”) (quoting 2 WILLIAM C. ROBINSON, *THE LAW OF PATENTS FOR USEFUL INVENTIONS* 459 (1890)) (attached as Exhibit 7).

Third, a section 291 action redresses Bayer's injury by removing the impairment caused by an interfering patent. *Kimberly-Clark*, 973 F.2d at 914-15. Here, Bayer asks the Court for a declaration that the interfering claims of the '984 patent are invalid because Bayer first invented the claimed subject matter. (D.I. 5, Am. Compl., Prayer for Relief at f-g.) Such a declaration would eliminate the interfering patent and restore Bayer's undivided right to exclude.

C. Warner Chilcott Cannot Graft Additional Requirements Upon Section 291

Warner Chilcott supports its motion to dismiss by attempting to graft additional requirements onto section 291 under the guise of Article III. As shown above, however, the impairment of Bayer's property interest in its patent due to Warner Chilcott's interfering patent is alone sufficient to meet the requirements of section 291 and establish Article III standing. There is no foundation for Warner Chilcott's assertion that Bayer must allege a priority dispute or some other claimed injury in order to bring an interference claim.

1. A dispute over priority is not necessary to maintain an interference action

Warner Chilcott claims that "in the absence of a genuine priority dispute, Warner Chilcott's '984 patent presents no actual, imminent threat to the validity of Bayer's '940 patent." WC Br. at 9. As a result, Warner Chilcott says that "the complaint fails to allege the necessary priority dispute required to establish subject matter jurisdiction under § 291." (*Id.*)

This argument misinterprets section 291. The statute provides a patent owner relief from an "interfering patent." 35 U.S.C. § 291. Determining priority of invention is secondary to whether an interference-in-fact exists. Thus, "[t]he first step in a § 291 interfering patents action is the determination whether an interference in fact exists between claims of the two patents." *Genetics Inst.*, 655 F.3d at 1302. The interference-in-fact inquiry is the primary inquiry because the "existence of interfering patents is intrinsically and inextricably a premise of a § 291 claim."

Bally Gaming, Inc. v. Kappos, 888 F. Supp. 2d 108, 111 (D.D.C. 2012) (discussing commentary of drafter of Patent Act). “If that premise fails, then the § 291 claim dependent thereon fails as well.” *Id.*

A priority determination only occurs if the Court determines that the patents claim interfering subject matter. *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 777 F. Supp. 779, 782 (N.D. Cal. 1991) (“[O]nce two or more patents are issued to different owners, and thereafter are found to contain interfering claims, i.e., both owners’ claims are directed to the same invention, the only way to resolve priority of inventorship is under 35 U.S.C. section 291.”) Unlike the interference-in-fact inquiry, a determination of priority is not jurisdictional or even the plaintiff’s burden. *See Medichem*, 437 F.3d at 1169. The party with the later effective filing date “bears the burden of establishing priority by a preponderance of the evidence” once interference is established. *Id.* Here, that burden is Warner Chilcott’s.

Warner Chilcott’s insistence that a dispute over priority is necessary for Article III standing misses the point of an interference action, which is to provide a patent owner relief from an “interfering patent.” Even where, as here, there is no dispute as to priority, a patent holder is entitled to ask a court to find an interference-in-fact and to invalidate the interfering patent. That Warner Chilcott appears to concede Bayer’s priority is irrelevant to the question before the court: whether there is an interference-in-fact between the ’940 patent and ’984 patent. Until that question is resolved, Warner Chilcott’s patent continues to interfere with Bayer’s full enjoyment of its property interest in the ’940 patent. Warner Chilcott cannot deny Bayer’s standing at the outset of the case by conceding an issue on which it bears the ultimate burden of proof.

2. An infringement suit is not necessary to establish Article III standing to maintain an interference action

Warner Chilcott also claims that Bayer lacks standing because it has not “allege[d] that it has been sued, or threatened with suit, for infringing the ’984 patent.” (WC Br. at 9.) But the Federal Circuit has already rejected the claim that an infringement suit (threatened or otherwise) is necessary to maintain an interference action. “[B]y its very language, a cause of action under section 291 does not require that ‘the owner of an interfering patent’ accuse ‘the owner of another’ of infringement. Rather, section 291 gives patent owners a separate and distinct basis of jurisdiction if two patents interfere.” *Kimberly-Clark*, 973 F.2d at 914. Such an action is proper “even when by agreement or otherwise, there is no infringement issue between the parties.” *Id.*

3. A section 291 action is not a nullity action

Warner Chilcott says that this action is an improper “nullity action” because Bayer’s objective is to invalidate Warner Chilcott’s patent. (WC Br. at 11.) But Warner Chilcott takes the quoted cases out of context and conflates the standards governing declaratory-judgment actions with interference proceedings.

Warner Chilcott cites *Albert v. Kevex Corp.*, 729 F.2d 757, 761 (Fed. Cir. 1984) for the proposition that a desire to invalidate a patent makes a section 291 action an improper nullity action. But Warner Chilcott misconstrues the nature of the nullity action identified by the *Albert* court. An interference action is not a “nullity action” simply because the interference action is motivated by a desire to invalidate the interfering patent. As the Federal Circuit stated in *Albert*, a nullity action would exist only if “validity were adjudicable under § 291 ***without regard to whether interference exist[ed]***.” 729 F.2d at 761 (emphasis added). A competitor cannot use section 291 to attack the validity of a patent where no interference-in-fact exists—which is not the case here. But unless the plaintiff thinks it is going to lose, a desire to invalidate a patent

always motivates an interference action because that is what happens when patents interfere. *See Kimberly-Clark*, 973 F.2d at 914.¹

In addition, Warner Chilcott cites the standard for maintaining a declaratory-judgment action as though that is relevant to an interference proceeding. (WC Br. at 11.) It is not. Section 291 is not “comparable to the declaratory judgment statute.” *Albert*, 729 F.2d at 761. Parties establish subject-matter jurisdiction under the Declaratory Judgment Act by demonstrating an imminent threat of an infringement lawsuit. Fear of a patent is not sufficient. *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1339 (Fed. Cir. 2008). As discussed above, maintaining an interference action does not depend on a pending or threatened suit for infringement. The standard for when a party has sufficient reason to fear an infringement suit has no bearing on standing to maintain an interference action.

4. Warner Chilcott’s conclusion that there are no “real-world consequences” to the interference begs the question

At base, Warner Chilcott’s claim that Bayer lacks Article III standing is a disagreement with the cause of action Congress provided in section 291. By claiming that there are no “real world consequences,” Warner Chilcott assumes its conclusion and ignores the impairment that exists to Bayer’s patent by virtue of the interference.

The parties’ patents do not exist in a vacuum. Bayer and Warner Chilcott sell competing oral contraceptive products. Warner Chilcott sells LoLoestrin FE under the ’984 patent. And

¹ Warner Chilcott’s use of ellipses when quoting *International Signal Co. v. Vreeland Apparatus Co.* indicates the lack of support for its nullity-action argument. WC Br. at 11; 278 F. 468, 470 (2d Cir. 1921). Warner Chilcott elides several sentences to make it appear as though the *International Signal* court said it will not entertain an interference suit when a junior party concedes priority. WC Br. at 11. But the court was in fact making two distinct points over three paragraphs: (i) a court will not engage in “a useless investigation of priority” when “there is no patentable invention;” and (ii) an interference action is not a declaratory-judgment action for invalidity absent interfering patents. *See* 278 F. at 470; *see also* Ex. 11, Comparison.

Bayer sells its own contraceptive with a 24-day active-pill regimen, YAZ. Bayer brought YAZ to market only after a significant expenditure that culminated in several patents, including the '940 patent. A patent rewards this innovation by granting an inventor an undivided right to exclude others for the term of the patent. 35 U.S.C. § 154 (a)(1).

But whether Bayer practices or licenses the '940 patent is irrelevant. “[I]t is the privilege of any owner of property to use or not use it, without question of motive.” *Cont’l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 429 (1908). And “the long-settled view” is that “the essence of a patent grant is the right to exclude others from profiting by the patented invention”—especially one’s competitor. *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980). That right to exclude is as all the more important when one’s competitor has a patent claiming interfering subject matter. *See Kimberly-Clark*, 973 F.2d at 914 (“The fact that the Patent and Trademark Office issued patents . . . on the same invention is a serious impediment to the enjoyment of this essential right to exclude.”). As discussed, the existence of an interfering patent impinges on that undivided right to exclude—however Bayer chooses to enjoy that right.

Regardless, none of these other “real-world consequences” matter for purposes of pleading an interference action. Section 291 provides that “[t]he owner of an interfering patent may have relief against the owner of another by civil action.” 35 U.S.C. § 291. Bayer has properly pled the elements of an interference action, which also suffice for Article III standing.

The Court should deny Warner Chilcott’s motion to dismiss.

II. A STAY IS INAPPROPRIATE

In the alternative, Warner Chilcott asks the Court to stay this litigation pending the outcome of a trial and ensuing appeal in the District of New Jersey. “In determining whether a stay is appropriate, the court’s discretion is guided by the following factors: ‘(i) whether a stay

would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (ii) whether a stay will simplify the issues in question and trial of the case; and (iii) whether discovery is complete and whether a trial date has been set.” *ImageVision.Net, Inc. v. Internet Payment Exch., Inc.*, CA 12-054-GMS-MPT, 2013 WL 663535, at *1 (D. Del. Feb. 25, 2013). Although omitted from its statement of the standard, Warner Chilcott also must demonstrate that denial of the stay would subject it to “a clear case of hardship or inequity” where “there is even a ‘fair possibility’ that a stay would prove detrimental to” Bayer. *Id.*

In its motion, Warner Chilcott overstates the potential for efficiency gains, understates the harm to Bayer, and makes no effort to claim hardship. Warner Chilcott’s proposal would subvert Bayer’s rights to clear title over subject matter of its patent in exchange for no gain.

A. Judicial Economy Does Not Favor A Stay

The New Jersey litigation will not resolve Bayer’s interference claim and thus will not simplify the issues in this case. Even after a trial and an appeal, the Court and the parties will not necessarily be any further along in resolving Bayer’s interference claim.

First, the circumstances in which the New Jersey litigation could advance any of the issues in this case are limited because Bayer is not a party to that litigation. For instance, the District of New Jersey’s determination that Warner Chilcott’s patent was valid in light of the ’940 patent would not bind Bayer or the Court. *Allen Archery, Inc. v. Browning Mfg. Co.*, 819 F.2d 1087, 1091 (Fed. Cir. 1987). Even if the Federal Circuit affirmed that conclusion, Bayer could still litigate the validity of Warner Chilcott’s patent. *See Mendenhall v. Cedarapids, Inc.*, 5 F.3d 1557, 1570 (Fed. Cir. 1993) (although not always inappropriate, “[t]his court has rejected *stare decisis* as generally inappropriate on the issue of validity of a patent”). Bayer is not a party to that litigation, and that litigation cannot bind Bayer upon a finding of validity. *See IteX, Inc. v.*

Mount Vernon Mills, Inc., No. 08 CV 1224, 2010 WL 3655990, at *2 (N.D. Ill. Sept. 9, 2010) (“Absent such a finding [of preclusive effect], granting the stay in this case would not streamline the litigation and would only put off the requisite fact-finding until a time when memories are less clear and evidence less fresh.”).

Second, differences between an interference action and the defense against an infringement claim further diminish the possibility that the New Jersey litigation will advance this case. An interference action requires a two-way test that examines whether Warner Chilcott’s patent’s claims are anticipated or obvious in light of Bayer’s patent’s claims and vice versa. Despite Warner Chilcott’s suggestion to the contrary, the two-way test and a typical anticipation or obviousness analysis are **not the same inquiries**. (WC Br. at 15.) Determining whether an interference exists requires looking **only** at the patents’ **claims** as construed. *Slip Track Sys., Inc.*, 304 F.3d at 1265; *Alberta Telecomm. Research Ctr. v. Rambus Inc.*, Case No. C-06-02595 RMW, 2007 WL 2317836, at *2-3 (N.D. Cal. Aug. 10, 2007). By contrast, anticipation and obviousness compare a patent’s claims to anything in the prior art to determine if there is disclosure of the claimed invention as well as look at other secondary considerations. 3 Annotated Patent Digest § 18:26 (“In evaluating a reference forming the bases of an obviousness challenge, the reference must be considered for all that it teaches, not just the particular invention that it claims or describes.”); *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012).

There is no reason to believe the District of New Jersey will focus solely on comparing the claims of Bayer’s patent to that of Warner Chilcott’s patent. Absent such a narrow review of Warner Chilcott’s patent, any conclusions of validity have no bearing on Bayer’s interference claim. For these reasons, at least one court has refused to transfer an interference action to

another jurisdiction where one patent owner had asserted an interfering patent against other accused infringers. *See Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 597 F. Supp. 2d 462, 469 (D. Del. 2009) (“The Texas litigation concerns infringement of the ’620 and ’447 patents, while plaintiff seeks a determination of priority vis-à-vis the ’112 patent in the case at bar. These issues are distinct and the court disagrees with defendant that its consideration of the latter issue will result in a ‘substantial duplication of judicial effort’ or a ‘risk of inconsistent judgments.’”).²

Finally, the ability for the New Jersey litigation to advance any issue in this case requires that the case proceed to trial or through appeal. Warner Chilcott may settle the New Jersey litigation at any point—eliminating even any marginal gains. Bayer has only identified one litigated patent case brought by Warner Chilcott that has ended in trial; the others appear likely to have ended in settlement. (Ex. 8, Lex Machina Docket Reports.) In fact, Warner Chilcott has settled every prior case in which it asserted the other patent at issue in the New Jersey litigation. (Ex. 9, DocketNavigator Report on U.S. Patent No. 5,552,394.) Warner Chilcott’s brief fails to even address the possibility that the New Jersey litigation would end in settlement. If the New Jersey litigation settles, even the modest potential efficiency gains of a stay will never materialize—although the corresponding delay is certain to occur.

² Warner Chilcott has not requested that this Court transfer to the District of New Jersey and, in any event, such a transfer would be improvident. The firm Fitzpatrick, Cella, Harper & Scinto represents Warner Chilcott in the New Jersey litigation. Fitzpatrick, Cella has also represented Bayer in matters relating to the 24-day regimen, making transfer to the District of New Jersey inappropriate.

B. A Stay Undermines Bayer's Rights

Regardless what the District of New Jersey concludes, the delay occasioned by Warner Chilcott's proposed stay would be substantial. Warner Chilcott estimates that "the New Jersey litigation will likely be resolved by the district court by the end of the year, with Federal Circuit review immediately following." (WC Br. at 18.)

Even crediting Warner Chilcott's description of events, the stay would delay Bayer's interference action by over a year. Trial will begin six months from today at the earliest. (D.I. 9, Morin Decl., Ex. 2.) The median time for the Federal Circuit to resolve an appeal is ten months from docketing of the appeal. (Ex. 10, Fed. Cir. Statistics, Median Disposition Time.) Even if the district court issues an opinion and the appeal is docketed the day after trial concludes, the Federal Circuit would still not reach a decision until July 2014. At that point Bayer could *begin* its interference case if Warner Chilcott's patent is upheld.

But this estimate is unrealistic. It assumes that trial will commence in September 2013 even though the trial date is listed as "[p]otential" and "[s]ubject to [the] Court's [a]vailability" (D.I. 9, Morin Decl., Ex. 2); that the New Jersey court issues an opinion the day after trial concludes; that no party files a post-trial motion; that parties do not wait before filing a notice of appeal; and that no other

Delay Before Bayer Can Begin Interference Lawsuit

Event	Timeframe
Potential Trial Date	September 2013
Time To Issue Opinion	---
Post-Judgment Motions	28 days from judgment
Time To Appeal	30 days from judgment or resolution of post-judgment motion
Median Appeal Time	10 months from docketing appeal

FRCP 60; FRAP 4(a)(1), (4); Ex. 10.

delays intervene to upset the current schedule. Any of these events would further delay Bayer's interference action into the second half of 2014 or beyond. At that point, Bayer could begin to

litigate its case. The effect of this delay will be to push the resolution of Bayer's interference action to the eve of or beyond the '940 patent's expiration in 2015. *Cf. St. Clair Intellectual Prop. Consultants, Inc. v. Fujifilm Holdings Corp.*, CIV. A. 08-373-JJF-LPS, 2009 WL 192457, at *2 (D. Del. Jan. 27, 2009) ("With the passage of time, St. Clair is likely to face evidentiary obstacles and the prospect of litigating an expired or nearly-expired patent.").

C. Warner Chilcott Has Not Demonstrated Any Burden From Litigating Bayer's Interference Action Now

Finally, Warner Chilcott has not met its burden that denial of the stay will work hardship or inequity. *ImageVision.Net, Inc.*, 2013 WL 663535, at *1. Warner Chilcott claims that proceeding with the interference action will subject it to "costly and time-consuming fact and expert discovery." (WC Br. at 16.)

But Warner Chilcott is not moving to stay the infringement portion of Bayer's case. Thus, the parties will engage in claim construction and discovery regarding one of the two patents at issue in the interference. *See Gen. Foods Corp. v. Struthers Scientific & Int'l Corp.*, 309 F. Supp. 161, 162 (D. Del. 1970) ("The factual background relating to the other two patents and the several claims of unfair competition are so intertwined that a stay of only a part of the litigation would not materially reduce the discovery and expenses of the other phases of the litigation not affected by the stay."). This will likely include expert discovery into the technology underlying both patents.

In addition, Warner Chilcott has already conducted discovery regarding its patent as part of the New Jersey litigation. (D.I. 9, Morin Decl., Ex. 2 (setting February 15, 2013 as close of fact discovery).) Apart from additional depositions, its document collection should be substantially complete with respect to its own patent. And Bayer is willing to work with Warner Chilcott to avoid unnecessary duplication of collection efforts.

The only additional work Warner Chilcott would need to perform would support the Court's comparison of the construed claims of the parties' patents to assess whether an interference-in-fact exists and to determine priority. That work does not justify a stay.

The Court should deny Warner Chilcott's request for a stay. It is undisputed that a stay will serve to delay and frustrate Bayer's efforts to protect its rights to exclusivity over the subject matter covered in the '940 patent. While the stay would undermine Bayer's rights, the gains to judicial efficiency of a stay would be slight, if they materialize at all. Further, Warner Chilcott has not shown "a clear case of hardship or inequity" would result from the denial of its motion.

CONCLUSION

For the foregoing reasons, the Court should deny Warner Chilcott's motions to dismiss or stay Bayer's interference actions.

April 4, 2013

BAYARD, P.A.

OF COUNSEL:

Matthew R. Ford
Andrew C. MacNally
BARTLIT BECK HERMAN
PALENCHAR & SCOTT LLP
54 W. Hubbard Street, Suite 300
Chicago, IL 60654
(312) 494-4400

/s/ Richard D. Kirk
Richard D. Kirk (rk0922)
Stephen B. Brauerman (sb4952)
Vanessa R. Tiradentes (vt5398)
222 Delaware Avenue, Suite 900
P.O. Box 25130
Wilmington, DE 19899
(302) 655-5000
rkirk@bayardlaw.com
sbraerman@bayardlaw.com
vtiradentes@bayardlaw.com

*Attorneys for Bayer Intellectual Property GmbH
and Bayer Pharma AG*